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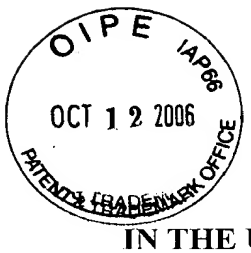


Docket No.: NY-QMET 201-US
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:
John E. Ware et al.

Application No.: 09/873,500

Filed: June 4, 2001

For: METHOD AND SYSTEM FOR HEALTH ASSESSMENT AND MONITORING

Confirmation No.: 5112

Art Unit: 3626

Examiner: C. M. Bleck

**RESPONSE TO NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Notification of Non-Compliant Appeal Brief mailed September 20, 2006 (copy attached). Applicant respectfully submits a revised Appeal Brief.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-0624, under Order No. NY-QMET 201-US (10104949).

Dated: October 12, 2006

Respectfully submitted,

By _____
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Application No. (if known): 09/873,500 Attorney Docket No.: NY-QMET 201-US

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| 09/873,500 | 06/04/2001 | John E. Ware | QMET-201 | 5112 |

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| EXAMINER | |
|---|---|
| ART UNIT | PAPER NUMBER |

DATE MAILED: 09/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Action Req'd Date Due
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Reminder 10/13/06

| Notification of Non-Compliant Appeal Brief (37 CFR 41.37) | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/873,500 | WARE ET AL. | |
| | Examiner | Art Unit | |
| | Carolyn M. Bleck | 3626 | |



*--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--*

The Appeal Brief filed on *27 June 2006* is defective for failure to comply with one or more provisions of 37 CFR 41.37.

To avoid dismissal of the appeal, applicant must file anamended brief or other appropriate correction (see MPEP 1205.03) within **ONE MONTH or THIRTY DAYS** from the mailing date of this Notification, whichever is longer. **EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136.**

1. ☐ The brief does not contain the items required under 37 CFR 41.37(c), or the items are not under the proper heading or in the proper order.

2. ☐ The brief does not contain a statement of the status of all claims, (e.g., rejected, allowed, withdrawn, objected to, canceled), or does not identify the appealed claims (37 CFR 41.37(c)(1)(iii)).

3. ☐ At least one amendment has been filed subsequent to the final rejection, and the brief does not contain a statement of the status of each such amendment (37 CFR 41.37(c)(1)(iv)).

4. ☒ (a) The brief does not contain a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number and to the drawings, if any, by reference characters; and/or (b) the brief fails to: (1) identify, for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function under 35 U.S.C. 112, sixth paragraph, and/or (2) set forth the structure, material, or acts described in the specification as corresponding to each claimed function with reference to the specification by page and line number, and to the drawings, if any, by reference characters (37 CFR 41.37(c)(1)(v)).

5. ☐ The brief does not contain a concise statement of each ground of rejection presented for review (37 CFR 41.37(c)(1)(vi))

6. ☐ The brief does not present an argument under a separate heading for each ground of rejection on appeal (37 CFR 41.37(c)(1)(vii)).

7. ☐ The brief does not contain a correct copy of the appealed claims as an appendix thereto (37 CFR 41.37(c)(1)(viii)).

8. ☐ The brief does not contain copies of the evidence submitted under 37 CFR 1.130, 1.131, or 1.132 or of any other evidence entered by the examiner **and relied upon by appellant in the appeal**, along with a statement setting forth where in the record that evidence was entered by the examiner, as an appendix thereto (37 CFR 41.37(c)(1)(ix)).

9. ☐ The brief does not contain copies of the decisions rendered by a court or the Board in the proceeding identified in the Related Appeals and Interferences section of the brief as an appendix thereto (37 CFR 41.37(c)(1)(x)).

10. ☒ Other (including any explanation in support of the above items):

*The brief fails to contain a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number and to the drawings, if any, by reference characters. Applicant refers to original claim 7, which has been cancelled. Applicant fails to refer to independent claims 1, 18, 35, and 39 .*

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:
John E. Ware et al.

Application No.: 09/873,500 | Confirmation No.: 5112

Filed: June 4, 2001 | Art Unit: 3626

For: METHOD AND SYSTEM FOR HEALTH ASSESSMENT AND MONITORING | Examiner: C. M. Bleck

# APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

As required under § 41.37(a), this brief is filed within two months of the Notice of Appeal filed in this case on April 27, 2006, and is in furtherance of said Notice of Appeal.

The fees required under § 41.20(b)(2) are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

The Final Rejection is dated January 27, 2006. Appeal was noted on April 27, 2006.

This brief contains items under the following headings as required by 37 C.F.R. § 41.37 and M.P.E.P. § 1206:

| | |
|---|---|
| I. | Real Party In Interest |
| II | Related Appeals and Interferences |
| III. | Status of Claims |
| IV. | Status of Amendments |
| V. | Summary of Claimed Subject Matter |
| VI. | Grounds of Rejection to be Reviewed on Appeal |
| VII. | Argument |
| VIII. | Claims |

## I. REAL PARTY IN INTEREST

The real party in interest for this appeal is:

**QualityMetric, Inc.**, the assignee of the subject application.

## II. RELATED APPEALS, INTERFERENCES, AND JUDICIAL PROCEEDINGS

To the best of the knowledge of appellants, appellants' legal representative, and assignee, there are no other appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

## III. STATUS OF CLAIMS

Claims 1-40 were filed with the original application.

Original claims 1, 10, 14, 17, 18, 27, 34, 35, 39 and 40 were amended, claims 7, 11, 16, 24 and 28 were cancelled, and claims 41-45 were added by way of amendment.

Claims 1-6, 8-10, 12-15, 17-23, 25-27 and 29-45 are pending, all have been finally rejected, and all are appealed from.

## IV. STATUS OF AMENDMENTS

A reply was filed after Final Rejection, but Appellants did not amend the claims.

## V. SUMMARY OF CLAIMED SUBJECT MATTER

The claimed subject matter relates to a method of assessing the health status or health care of a patient, or to a method of dynamically administering a test to assess one or more domains. The present invention provides flexibility in the administration of the test by mimicking the evaluation process performed by a professional health care provider. That is, the threshold is varied during the test and the test is dynamically modified based on an

answer provided to an immediately prior question if the estimated confidence level is outside a threshold, as called for in claims 1, 18, 35, and 39. *See, e.g.,* page 47, lines 18-19.

The present method also comprises generating a customized test, which is based on the patient's characteristics and one or more health domains selected by the patient or health care provider, and contains a plurality of questions for the patient in accordance with the selected health domain. The test is administered by providing one question at a time to the patient, and after each question, answers provided by the patient to the administered questions are evaluated to estimate a score and a confidence level in the accuracy of the estimated score, as called for in claims 1, 18, 35 and 39. *See, e.g.,* page 15, lines 9-10; page 28, lines 9-12; page 34, lines 5-20, 22-23.

The claimed subject matter also relates to a computer based system for assessing the health status or health care of a patient, and a computer readable media for controlling a computer to perform the features recited *supra*, as called for in claim 39. *See, e.g.,* page 34, lines 5-20, 22-23, and pages 40-41.

## VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

All claims have been rejected under 35 U.S.C. § 103 over Ware et al. entitled "The Search for More Practical and More Precise Outcomes Measures," The Quality of Life Newsletter, January-April 1999 (Ware) and in view of U.S. Patent No. 6,067,523 to Bair et al. (Bair). This may be seen at page 3 of the Final Office Action.

It is believed that this rejection is in error, and reversal is requested.

## VII. ARGUMENT

Claims 1-6, 8-10, 12-15, 17-23, 25-27 and 29-45 have been rejected under 35 U.S.C. § 103 over Ware and Bair, and will be argued together.

To establish a prima facie case of obviousness, three basic criteria must be met. First there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be reasonable expectation of success.

Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP 2143. However, the claimed combination cannot change the principle of the operation of the reference or render the reference inoperable for its intended purpose. (MPEP § 2143.01 citing In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) and In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)).

### A. Combined References Do Not Teach Or Suggest All The Claim Limitations

The Examiner has failed to establish a prima facie case of obviousness because the combination of Ware and Bair does not teach or suggest all the claim limitations of claims 1, 18, 35 and 39.

#### 1. Neither Ware Nor Bair, Independently Or In Combination Therewith, Teach Or Suggest A Threshold Which Varies As A Function Of The Estimated Score During The Administration Of A Test

Appellants respectfully submit that only the present invention teaches or suggests varying the threshold as a function of the estimated score, as required by independent claims 1, 18, 35, and 39.

Appellants submit that Ware merely describes a health assessment method that utilizes a fixed, unvarying, set or preset standard of precision (i.e., threshold) within a single health assessment, whereas the present invention provides a method of assessing the health status or health care of a patient wherein the threshold varies as a function of the estimated score within or during a single test.

The Examiner asserts that "Ware teaches that the threshold (i.e., precision standard based on the confidence interval) varies as a function of the estimated score." (Final Office Action, page 4). For support regarding the Examiner's position, the Examiner cites to Ware at page 12 col. 1-2 and states:

> Ware discloses determining whether the score has been estimated within a preset standard of precision based on the confidence interval, wherein once the precision standard is met, the computer either begins assessing the next concept or ends the battery (considered to be a form of 'threshold'), wherein the precision standard based on the confidence interval (i.e., the threshold) is set based on each patient's score. ... Note, Ware's discussion of where the preset standard of precision is +/-5.4 for the lowest scoring patients, where these patients scored near or below an established cutoff point used in screening patients for psychiatric disorders. Note, that Ware discloses that the standard of precision was relaxed to +/-7.9 or less for patients at or above the $90^{th}$ percentile.

(Final Office Action, page 3) (emphasis added).

Contrary to the Examiner's assertion, these sections of Ware cited by the Examiner do not show that the threshold varies during the administration of the test. These cited passages merely show that Ware sets different precision standards for different groups of patients (low vs. high scoring patients). In fact, these passages from Ware cited by the Examiner clearly supports appellants position that Ware does not teach or suggest varying the threshold during the administration of a test. This, of course, is a feature recited by independent claims 1, 18, 35 and 39 of the present invention.

Moreover, appellants respectfully submit that one of ordinary skill in the art would not find that modifying the different preset precision standards in Ware, which are fixed for different groups of patients (low vs. high scoring patients), is equivalent to varying the threshold during a single test as a function of the estimated score as required by independent claims 1, 18, 35 and 39 of the present invention. Therefore, the Examiner has failed to show that Ware teaches or suggests varying the threshold as a function of the estimated score during that administration of a test.

The Examiner admits that Ware et al. does not describe the health domains being selected by a patient or a health care provider as required by the pending claims. (Final Office Action, Page 4). To cure this deficiency, the Examiner turns to Bair. (*Id.*) However, Bair does not teach or suggest varying the threshold as a function of the estimated score during the administration of a test. This, of course, as noted supra, is a feature recited by independent claims 1, 18, 35 and 39 of the present invention.

Bair merely describes generating a test from a master question table and skipping certain related questions based on the answer to the first related question. *See* col. 11, line 45 - col. 13, line 12. For example, if the patient answers that she has no history of drug abuse, then the drug related questions (i.e., what drugs are you taking) will be skipped. There is no disclosure in Bair related to use of a threshold or a precision standard. Hence, Bair does not teach or suggest varying the threshold as a function of the estimated score during the administration of a test. Therefore, the addition of Bair does not cure the aforenoted deficiency of Ware, and the combination of Ware and Bair does not teach or suggest varying the threshold as a function of the estimated score as required by independent claims 1, 18, 35 and 39.

Accordingly, appellants respectfully submit that the Examiner has failed to establish the basic requirements of a prima facie case of obviousness because Ware and Bair independently or in combination therewith do not describe all the claim limitations of the pending claims. Therefore, appellants respectfully submit that independent claims 1, 18, 35 and 39 (and dependant claims 2-6, 8-10, 12-15, 17, 19-23, 25-27 and 29-34, 36-38, 40-45) are nonobvious under 35 U.S.C. § 103.

**B. There Is No Motivation To Combine Prior Art**

The Examiner has also failed to establish a prima facie case of obviousness because there is no motivation in Ware or in Bair that the teaching of these two references should be combined. Ware and Bair fail to suggest the desirability of the claimed invention because it is undeniable that neither Ware nor Bair is even remotely concerned with the problem of providing flexibility in the administration of the test by mimicking the evaluation process performed by a professional health care provider. Typically, the health care provider administering the test may inquire more deeply into certain issues (related to specific domains) raised by the patient's answer if the patient scored poorly, whereas additional questions related to domains which are of reduced interest would not be asked. For example, if a person has difficulty walking up the stairs due to leg pain without shortness of breath or chest pain, a health care provider will want to gather more information regarding the leg pain. This could be done by more focused questions directed to the history of the leg pain, e.g., how long have you had the pain, how severe is the pain on a scale of 1-10, when does it hurt the most, and by ordering further tests like an x-ray or MRI. The health care provider will

not inquire further regarding possible issues related to shortness of breath or chest pain, because it was found out that this is not the reason that the patient is having difficulty walking up the stairs.

The present invention attempts to provide such flexibility by varying the threshold as a function of the estimated score during the test. In particular, during the administration of the test, the threshold will be raised for a domain of particular interest and will be lowered for a domain of lesser interest. In so doing, the present invention streamlines the process by not requiring an unnecessary amount of additional questions for domains which are of reduced interest, while requiring an increased number of questions related to a domain of particular interest. This aspect of the present invention can raise the statistical accuracy and focus of the test, while at the same time reducing the burden on the test subject.

It is undeniable that Ware or Bair individually or in combination therewith is not even remotely concerned with providing such flexibility. Since Appellants have recognized a problem not addressed by the cited prior art and solved that problem in a manner not suggested by cited prior art, the basis for patentability of the claims is established. See In re Wright, 6 U.S.P.Q. 2d, 1959, 1961-1962 (Fed. Cir. 1988). There, the CAFC relied upon previous decisions requiring a consideration of the problem facing the inventor in reversing the Examiner's rejection. "The problem solved by the invention is always relevant". Id. at 1962. See also, In re Rinehart, 189 U.S.P.Q. 143, 149 (CCPA 1967), which stated that the particular problem facing the inventor must be considered in determining obviousness.

Absent evidence that the specific problem was recognized and solved by providing such flexibility of mimicking the health care professional's evaluation process during the administration of the test, there can be no finding that the invention as a whole would have been obvious. As stated by the PTO Board of Appeals in Ex parte Breidt and Lefevre, 161 U.S.P.Q. 767, 768 (1968), "an inventive contribution can reside as well in the recognition of a problem as in a solution". It further appears that the conclusion reached by the Board of Appeals in Ex parte Minks, 169 U.S.P.Q. 120 (1969), is here in point. There, the Board concluded that "[a]ppellant having discovered the source of the problem and solved the same ... he is... entitled to patent protection". Id. at 121.

## VIII. CLAIM APPENDIX

A copy of the claims involved in the present appeal is attached hereto as Appendix A. As indicated above, the claims in Appendix A do include the amendments filed by Applicant on November 10, 2005.

## IX. EVIDENCE APPENDIX

No evidence pursuant to §§ 1.130, 1.131, or 1.132 or entered by or relied upon by the examiner is being submitted.

## X. CONCLUSION

It is respectfully submitted, in light of above, all pending claims 1-6, 8-10, 12-15, 17-23, 25-27 and 29-45 are nonobvious under 35 U.S.C. §103 because the Examiner failed to establish a prima facie case of obviousness. Therefore, appellants request that the Board reverse the pending grounds for rejection.

## XI. RELATED PROCEEDINGS

No related proceedings are referenced in II. above, or copies of decisions in related proceedings are not provided, hence no Appendix is included.

Dated: October 12, 2006

Respectfully submitted,

By _____
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## APPENDIX A

**Claims Involved in the Appeal of Application Serial No.** 09/873,500

1. A method of assessing the health status or health care of a patient, comprising the steps of:

generating a customized test, based on the patient's characteristics and one or more health domains selected by a patient or a health care provider, said test having a plurality of questions for said patient in accordance with said selected health domains;

administering said test by providing one question at a time to said patient; and

after each question, evaluating answers provided by said patient to administered questions to estimate a score and a confidence level in the accuracy of said estimated score and dynamically modifying said test based on an answer provided to an immediately prior question if said estimated confidence level is outside a threshold and wherein said threshold varies as a function of said estimated score.

2. The method of claim 1, further comprising the step of generating a report regarding the health status of said patient.

3. The method of claim 1, wherein said domain is a condition experienced or perceived by said patient.

4. The method of claim 1, wherein the step of dynamically modifying includes the step of ranking said plurality of questions in accordance with said estimated score; and selecting a question from said plurality of questions based on said ranking that has not been administered to said patient.

5. The method of claim 4, wherein the step of selecting comprises selecting a highest rank question.

6. The method of claim 1, wherein the step of dynamically modifying includes the step of terminating said administration of said test if it is determined that said estimated confidence level is within said threshold.

8. The method of claim 1, wherein the step of generating selects said questions for said domain from a database having questions and answers pertaining to a plurality of domains.

9. The method of claim 1, wherein the step of administering includes the step of providing a list of possible answers for each question to said patient.

10. The method of claim 1, wherein the step of estimating includes the step of statistically analyzing said answers provided by said patient for errors or consistency.

12. The method of claim 1, wherein the step of estimating includes the step of statistically analyzing said answers provided by said patient for estimating non-responsive answers to said test.

13. The method of claim 2, wherein the step of reporting includes the step of comparing said answers provided by said patient with answers provided by other patients in said domain.

14. The method of claim 1, wherein the step of administering includes the step of administering said test to said patients over a network, wherein said network is one of the following: an Internet, an intranet, a telephone network, and a wireless network.

15. The method of claim 2, wherein the step of generating reports includes the step of generating said report over a network.

17. The method of claim 1, wherein said domain includes at least one of the following: severity of headaches, level of depression, degree of personal mobility, self-perceived status, effectiveness of a treatment, physical health, emotional health, impact of asthma, job satisfaction, opinion polling, personality test, customer satisfaction and general overall health.

18. A computer based system for assessing the health status or health care of a patient, comprising:

a test module for generating a customized test, based on the patient's characteristics and one or more health domains selected by a patient or a health care

provider, said test having a plurality of questions for said patient in accordance with said selected health domains;

an administration module for administering said test by providing one question at a time to said patient; and

an evaluation module for evaluating, after each question, answers provided by said patient to administered questions to estimate a score and a confidence level in the accuracy of said estimated score; and wherein said evaluation module is operable to dynamically modify said test based on an answer provided to an immediately prior question if said estimated confidence level is outside a threshold and wherein said threshold varies as a function of said estimated score.

19. The system of claim 18, further comprising a report module for generating a report regarding the health status of said patient.

20. The system of claim 18, wherein said domain is a condition experienced or perceived by said patient.

21. The system of claim 18, wherein said evaluation module is operable to rank said plurality of questions in accordance with said estimated score and select a question from said plurality of questions based on said ranking that has not been administered to said patient.

22. The system of claim 21, wherein said evaluation module is operable to select a highest rank question.

23. The system of claim 18, wherein said administration module is operable to terminate said administration of said test if it is determined that said estimated confidence level is within said threshold.

25. The system of claim 18, wherein said test module is operable to generate said questions for said domain from a database having questions and answers pertaining to a plurality of domains.

26. The system of claim 18, wherein said administration module is operable to provide a list of possible answers for each question to said patient.

27. The system of claim 18, wherein said evaluation module is operable to statistically analyze said answers provided by said patient for errors or consistency.

29. The system of claim 18, wherein said evaluation module is operable to statistically analyze said answers provided by said patient for estimating non-responsive answers to said test.

30. The system of claim 19, wherein said reporting module is operable to compare said answers provided by said patient with answers provided by other patients in said domain.

31. The system of claim 18, wherein said administration module is operable to administer said test to said patients over a network.

32. The system of claim 19, wherein said reporting module is operable to generate said report over a network.

33. The system of claim 31, wherein said network is one of the following: an Internet, an intranet, a telephone network, and a wireless network.

34. The system of claim 18, wherein said domain includes at least one of the following: severity of headaches, level of depression, degree of personal mobility, self-perceived status, effectiveness of a treatment, physical health, emotional health, impact of asthma and general overall health.

35. A method of dynamically administering a test to assess one or more domains, comprising the steps of:

generating a customized test, based on a respondent's characteristics and one or more domains selected by the respondent or test provider, said test having a plurality of questions for said respondent in accordance with said selected domains;

administering said test by providing one question at a time to said respondent; and

after each question, evaluating answers provided by said respondent to administered questions to estimate a score and a confidence level in the accuracy of said estimated score and dynamically modifying said test based on an answer

provided to an immediately prior question if said estimated confidence level is outside a threshold and wherein said threshold varies as a function of said estimated score.

36. The method of claim 35, wherein the step of dynamically modifying includes the step of terminating said administration of said test if it is determined that said estimated confidence level is within said threshold.

37. The method of claim 35, wherein said domain is one or more health related or non-related conditions.

38. The method of claim 37, wherein said domain includes at least one of the following: severity of headaches, level of depression, degree of personal mobility, self-perceived status, general overall health, effectiveness of a treatment, job satisfaction, opinion polling, personality test, and customer satisfaction.

39. A computer readable media for controlling a computer to perform the steps of:

generating a customized test, based on the patient's characteristics and one or more health domains selected by a patient or a health care provider, said test having a plurality of questions for said patient in accordance with said selected health domains;

administering said test by providing one question at a time to said patient; and

after each question, evaluating answers provided by said patient to administered questions to estimate a score and a confidence level in the accuracy of said estimated score and dynamically modifying said test based on an answer provided to an immediately prior question if said estimated confidence level is outside a threshold and wherein said threshold varies as a function of said estimated score.

40. The computer readable media of claim 39, wherein the step of dynamically modifying includes the step of terminating said administration of said test if it is determined that said estimated confidence level is within said threshold.

41. The method of claim 1, wherein at least two domains are selected to be assessed.

42. The method of claim 1, wherein said step of administering said test further comprises the step of administering said test before a variable is introduced, wherein said variable includes one of the following: a pharmaceutical, drug composition change,

therapeutic method, health care provider, health care regimen, environmental change, lifestyle change, or work change, and further comprising the steps of:

readministering said test after said variable is introduced; and

comparing resultant data obtained from each separate administration of said test, wherein said resultant data is indicative of efficacy or impact of the introduction of said variable on said health status or health care of said patient.

43. The computer based system of claim 18, wherein said administration module is operable to:

administer said test before a variable is introduced, wherein said variable includes one of the following: a pharmaceutical, drug composition change, therapeutic method, health care provider, health care regimen, environmental change, lifestyle change, or work change;

readminister said test after said variable is introduced; and

wherein said system further comprises a comparison module for comparing resultant data obtained from each separate administration of said test by said administration module, wherein said resultant data is indicative of efficacy or impact of the introduction of said variable on said health status or health care of said patient.

44. The method of claim 35, wherein said step of administering said test further comprises the step of administering said test before a variable is introduced, wherein said variable includes one of the following: a pharmaceutical, drug composition change, therapeutic method, health care provider, health care regimen, environmental change, lifestyle change, or work change, and further comprising the steps of:

readministering said test after said variable is introduced; and

comparing resultant data obtained from each separate administration of said test, wherein said resultant data is indicative of efficacy or impact of the introduction of said variable on said health status or health care of said respondent.

45. The computer readable media of claim 39, wherein said step of administering said test further comprises the step of administering said test before a variable is introduced, wherein said variable includes one of the following: a pharmaceutical, drug composition change, therapeutic method, health care provider, health care regimen,

environmental change, lifestyle change, or work change, and further comprising the steps of:

readministering said test after said variable is introduced; and

comparing resultant data obtained from each separate administration of said test, wherein said resultant data is indicative of efficacy or impact of the introduction of said variable on said health status or health care of said patient.

**EVIDENTIARY APPENDIX**
**(37 C.F.R. § 41.37(C)(IX)**

None.

## RELATED PROCEEDINGS
## (37 C.F.R. § 41.37(C)(XI)

None.